

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Acute and chronic effects of a course of aerobic exercise training and garlic supplementation on serum levels of interleukin 6 (IL6), erythrocyte sedimentation rate (ESR) and fatigue in women with Rheumatoid Arthritis

Protocol summary

Study aim

Evaluation of acute and chronic effects of aerobic exercise and garlic supplementation on serum levels of interleukin 6 (IL6), erythrocyte sedimentation rate (ESR) and fatigue in women with rheumatoid arthritis

Design

A clinical trial with parallel, double-blind, randomized groups on 45 patients. The variable block method is used for randomization.

Settings and conduct

The training program will include 8 weeks of work with a ergometer bicycle, 3 sessions/week and each session for 60 minutes with a heart rate of 70% of the maximum heart rate. Exercise+supplement group, in addition to exercise, receive garlic supplement (at a dose of 500 mg twice/day). Exercise group+placebo, in addition to exercise, receive starch with a garlic-like appearance, and the supplement group, only receives garlic supplements. Exercises will performed in the Moin Stadium of Sistan and Baluchestan University and diagnostic tests are performed in the laboratory of Dr. Dabiri in Zahedan. For blindness, subjects and evaluators will be unaware of the exercise+placebo and supplement+exercise groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Catching Rheumatoid arthritis

Exclusion Criteria: Cardiovascular disease, pregnancy and menopause

Intervention groups

1- Exercise group: 8 weeks of work with a ergometer bicycle, 3 sessions per week and each session for a duration 60 minutes with a heart rate of 70% of the maximum heart rate. 2- Exercise+supplement group: In addition to the 8-week exercise program, they also take garlic supplements for 8 weeks (at a dose of 500 mg twice a day). 3- Supplement group: receives only garlic supplement for 8 weeks.

Main outcome variables

Serum levels of IL-6; Erythrocyte sedimentation rate and changes in fatigue due to aerobic exercise and garlic supplementation in rheumatoid arthritis.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180923041097N4**

Registration date: **2021-11-27, 1400/09/06**

Registration timing: **retrospective**

Last update: **2021-11-27, 1400/09/06**

Update count: **0**

Registration date

2021-11-27, 1400/09/06

Registrant information

Name

Reza Delavar

Name of organization / entity

The University of Sistan and Baluchestan

Country

Iran (Islamic Republic of)

Phone

+98 54 3113 2674

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delavar@ped.usb.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-11, 1400/06/20

Expected recruitment end date

2021-09-16, 1400/06/25

Actual recruitment start date

2021-11-06, 1400/08/15

Actual recruitment end date

2021-11-11, 1400/08/20

Trial completion date

2022-03-11, 1400/12/20

Scientific title

Acute and chronic effects of a course of aerobic exercise training and garlic supplementation on serum levels of interleukin 6 (IL6), erythrocyte sedimentation rate (ESR) and fatigue in women with Rheumatoid Arthritis

Public title

The effect of aerobic exercise and garlic supplementation on interleukin 6 (IL6), erythrocyte sedimentation rate (ESR) and fatigue in women with rheumatoid arthritis

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Rheumatoid arthritis patients Women who are menstruating The age range of 25 - 45 years

Exclusion criteria:

Cardiovascular disease Menopausal women

Age

From **27 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **45**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation method used with variable blocks. 3 groups of 15 people were considered and the subjects were randomly divided into three groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

- Participants in the experimental groups (supplement and placebo) are unaware of taking the supplement or placebo. - In addition to participants, outcome assessors are unaware of complementary and placebo groups

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee, Sistan and Baluchestan University

Street address

Central Organization of Sistan and Baluchestan University, University Blvd.

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

۹۸۱۶۷۴۵۸۴۵

Approval date

2021-04-22, 1400/02/02

Ethics committee reference number

IR.USB.REC.1400.020

Health conditions studied**1****Description of health condition studied**

Rheumatoid Arthritis

ICD-10 code

M05.049

ICD-10 code description

Felty's syndrome, unspecified hand

Primary outcomes**1****Description**

Inflammatory factor interleukin-6, the amount of which is above 20 pg/ml by ELISA kit.

Timepoint

24 hours before the first session of the exercise training program and 24 hours after the last session of the exercise training program.

Method of measurement

Interleukin-6 ELISA kit

2**Description**

Erythrocyte Sedimentation Rate above 35 mm/hr.

Timepoint

24 hours before and 24 hours after the first session and the last session of the exercise training program.

Method of measurement

Westergren method.

3

Description

Fatigue rate, which was considered above 3 on average

Timepoint

24 hours before and 24 hours after the first session and the last session of the exercise training program.

Method of measurement

Fatigue Severity Inventory (FSI) Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: A group that performs 8 weeks of aerobic exercise, 3 sessions per week and 1 hour per session with an intensity of 70% of the maximum heart rate on the ergometer bicycle.

Category

Behavior

2

Description

Intervention group 2: The group that in addition to aerobic exercise training also receives a garlic supplement at a dose of 500 mg, twice a day.

Category

Treatment - Other

3

Description

Intervention group 3: The group that receives only garlic supplement at a dose of 500 mg twice a day for 8 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abitaleb Hospital

Full name of responsible person

Mahnaz Sandoughi

Street address

Persian Gulf Highway - Salamat Boulevard - Ali Ibn Abitaleb Hospital

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Sistan-va-Balouchestan

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Fax

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Mahnaz Sandoughi

Street address

ZAUMS Main campus, Zahedan, Sistan and Baluchestan, Iran

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Web page address

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

University of Sistan and Baluchestan

Full name of responsible person

Reza Delavar

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

Street address

Department of Sport Sciences, Faculty of Psychology and Educational Sciences, University of Sistan and Baluchestan, , University Blvd.

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data related to the subjects after their non-identification and information data related to the main outcome

When the data will become available and for how long

From 2023/03/11

To whom data/document is available

Researchers working in universities

Under which criteria data/document could be used

All interested researchers

From where data/document is obtainable

By email address: delavar@ped.usb.ac.ir

What processes are involved for a request to access data/document

After reviewing the application received by the scientific responsible for research, the request will be answered via email.

Comments